

## REMARKS

### Claims

Claims 1-9, 11-24 and 26-31 are currently pending in the present application.

Claims 4-7 have been withdrawn from consideration.

No amendments have been made in the instant Request for Reconsideration.

### Rejection Under 35 U.S.C. § 103(a)

The Examiner has rejected claims 1-3, 8-9, 11-24 and 26-31 under 35 U.S.C. § 103(a) as being unpatentable over Westerlund *et al.* (*Carbohydrate Polymers* **20**:115-123, 1993) or Bhatt y (US 5,518,710) in view of Jamas *et al.* (US 5,622,939). Applicants traverse this rejection.

Westerlund *et al.* discloses a method that involves dialysis of a beta-glucan containing fraction using a dialysis tubing having a 12 kDa molecular weight cut-off to produce a purified liquid extract containing mixed-linked beta-glucans. See, page 116, right column, lines 47-53.

Bhatt y discloses a method that includes removal of degraded starches from a beta-glucan extract using centrifugation, dialysis or filtration. See, column 3, lines 63-65. The method of Bhatt y would not, however, result in the isolation of  $\beta$  (1-3)  $\beta$  (1-4) glucan having a particle size of less than 0.2  $\mu\text{m}$ , but rather a composition that comprises  $\beta$  (1-3)  $\beta$  (1-4) glucans having a broader range of particle sizes.

Jamas *et al.* discloses a process for producing an aqueous soluble  $\beta$ (1-3) glucan in triple helix conformation, which includes a step of purifying denatured protein to remove aqueous insoluble glucan and aggregated aqueous soluble glucans by ultrafiltration with a 1000 to 100,000 MW cutoff and a step of purifying re-annealed soluble glucan by size fractionation using separate steps of ultrafiltration with a 30,000 to 100,000 MW cutoff and a 150,000 to 500,000 MW cutoff to remove high and low molecular weight soluble glucans selectively. The Examiner's attention is directed to [www.millipore.com/immunodetection/id3/concentration](http://www.millipore.com/immunodetection/id3/concentration) for an illustration of the molecular weight cutoffs associated with ultrafiltration membranes having pore sizes of between 0.001  $\mu\text{m}$  and 0.1  $\mu\text{m}$ . A copy of this webpage is attached for the convenience of the Examiner. Jamas *et al.* also indicates that the final glucan solution can be

sterilized by filtration through a 0.22  $\mu\text{m}$  filter, however, as this filtration step is conducted after the fractionation steps described above it would not result in any fractionation of the glucan material. Jamas *et al.* does not teach or suggest the fractionation of a beta glucan solution using a single step of filtration through a 0.22  $\mu\text{m}$  filter. Jamas *et al.* therefore teaches a method that involves using multiple ultrafiltration steps to produce a glucan solution having a narrower range of particle sizes than that of the  $\beta(1-3)\beta(1-4)$  glucan defined in the presently claimed pharmaceutical composition

Based on the foregoing, Applicants submit that the cited references do not teach or suggest, individually or in combination, a method that can produce a purified extract comprising  $\beta(1-3)\beta(1-4)$  glucan having a particle size of equal to or less than 0.2  $\mu\text{m}$  as a filtrate, for example, a method that includes using a *single step of* microfiltration with a cutoff of 0.2  $\mu\text{m}$  to filter out particulate material having a particle size of greater than about 0.2  $\mu\text{m}$  from an extract of  $\beta(1-3)\beta(1-4)$  glucan. Thus, Applicants submit that the combination of Westerlund *et al.*, Bhatti and Jamas *et al.* does not render the claimed subject matter obvious.

In view of the above remarks, Applicant submits that the claimed subject matter is not obvious from the combination of Westerlund *et al.* or Bhatti and Jamas *et al.* Withdrawal of this rejection is requested.

## **Conclusion**

In view of the above amendments and remarks, Applicants believe that the present claims satisfy the provisions of the patent statutes and are patentable over the cited prior art.

Application Serial No. 10/554,290  
Request for Reconsideration dated 8 September 2009  
Reply to Office Action dated 11 June 2009

Reconsideration of the application and early notice of allowance are requested. The Examiner is invited to telephone the undersigned to expedite the prosecution of the application.

Respectfully submitted,  
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Attachment: Webpage for [www.millipore.com/immunodetection/id3/concentration](http://www.millipore.com/immunodetection/id3/concentration).